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Title: Method and Device for Monitoring the Thermal Load on the Tissue in a Patient

In order that a method for monitoring the thermal load on the tissue in a patient in the area of application of a neutral electrode of a high-frequency treatment device is provided, it is proposed that the HF current flowing *via* the neutral electrode is measured, a signal corresponding to the square of this current is generated, this signal is fed during the whole treatment duration to an integrator and integrated thereon, and that generated integration signal is used as a measure for the thermal load on the tissue. A device for the realization of this method is also provided.

Description

The invention relates to a method for monitoring the thermal load on the tissue in a patient in the area of application of a neutral electrode of a high-frequency treatment device as well as a device for carrying out this method.

High-frequency treatment devices are used in surgery in order that certain regions of the body are strongly heated. High-frequency current is therein supplied to a certain region of the body to be treated *via* a working electrode, the high-frequency current is again supplied from the body to the high-frequency device *via* a neutral electrode. While the high-frequency current should generate a local heating in the area of the working electrode, this is not desired in the area of the neutral electrode. Based on the transition resistance in the application area of the neutral electrode at the body of the patient, a

heating can however not be avoided and may under certain circumstances lead to undesired tissue damages.

In order to keep this heating as low as possible, it is already known to provide the neutral electrodes with large surfaces and to thereby reduce the current density in the area of application.

It is further known to determine the capacity of a high-frequency device during the treatment in that the voltage between the electrodes connected to the body is determined, on the one hand, and the current flowing through these electrodes is determined, on the other hand, so that the power respectively output depending on the resistance of the tissue switched into the circuit is measured and can be used for controlling the output power of the high-frequency device (WO95/09577). This method allows to consider tissue changes in the treatment area, *e.g.* by evaporation of liquid, which lead to a change of the ohmic resistance of the tissue and, thereby, also to a change of the power output in the operation area. The heat development in the area of the neutral electrode can in no way be determined or affected thereby.

It is the object of the invention to indicate a method by which the thermal load on the tissue in a patient in the area of application of a neutral electrode of a high-frequency treatment device can be determined.

In a method according to the invention, this object is solved in that the HF current flowing through the neutral electrode is measured, a signal corresponding to the square of this current is generated, this signal is fed during the whole treatment duration to an integrator and integrated thereon and that the integration signal generated is used as a measure for the thermal load on the tissue.

The integration signal obtained in this manner is a measure for the energy which is converted to heat in the area of the neutral electrode during treatment since this energy results from a product of the switching-on time, the transition resistance neutral electrode / body tissue and the square of the momentary value of the HF current in the neutral electrode. This momentary value of the HF current changes during the treatment duration depending on the respective treatment activity and the parts of the tissue to be treated, so that, as a whole, a measure for the heat generated in the area of the neutral electrode during the whole treatment duration is available by an integration of the squares of the changing HF current.

The HF current flowing through the neutral electrode can directly be determined by a current measurement in the line leading from the treatment unit to the neutral electrode.

However, it is in principle also possible to determine the value of the HF current flowing through the neutral electrode indirectly, *e.g.* by a measurement of the HF current on the primary side of the HF circuit, that is, in the treatment unit itself, or by a measurement of the supply current flowing to the treatment unit, the current may also be direct current.

It is particularly advantageous here if the integration signal is continuously reduced over the entire treatment period. This reduction corresponds to a cooling-down in the application area of the neutral electrode, this cooling-down can be realized by heat emission to the environment, by heat dissipation through body liquids or by heat conductance in the tissue of the body, it will take place during the whole treatment duration so that it is expedient to continuously reduce the integration signal generated in the manner as described above during the whole treatment duration in order to accommodate to this cooling-down.

The first embodiment can therefore provide that the integration signal is reduced by the same amount per unit of time; this corresponds to the approximated assumption that the heat dissipation in the application area of the neutral electrode remains constant over the period. It may however also be provided that the integration signal is reduced by an amount per unit of time which is proportional to the integration signal at the beginning of the unit of time. This would consider the fact that the heat dissipation in the application area of the neutral electrode is in fact proportional to the temperature achieved in this area, *i.e.* that it turns out higher if the heating in this area is higher, and this is represented by the integration signal.

It can further be provided that the value of the signal corresponding to the square of the HF current and/or the value of the integration signal during the treatment period is fed to a data memory and stored in certain time intervals. This allows to obtain a complete documentation of the amount of energy converted to heat or of the heating in the application area of the neutral electrode per unit of time, so that these processes can be exactly checked and reproduced also after the end of the treatment period.

It is expedient if the integration signal is compared with a maximum value and an indication device and/or switching-off device for the HF current is actuated when this maximum value is exceeded. Since the integration signal is a measure of the heating of the application area, it can be ensured thereby that the treated person will be warned when a

maximum heating is obtained in this area, or the HF current is completely switched-off in order that a further heating is avoided.

The indicated problem can be solved by a monitoring circuit for determining the thermal load on the tissue in a patient in the area of application of a neutral electrode of a high-frequency treatment device which is characterized by a measuring device for determining the HF current flowing *via* the neutral electrode, by a square-law transfer unit for generating a signal corresponding to the square of this current, and by a memory for integrating this signal over the whole treatment period for generating an integration signal as a measure for the thermal load on the tissue.

The value of the HF current flowing through the neutral electrode can be determined by a current measuring device in the line leading from the treatment unit to the neutral electrode. In an amended embodiment, it is provided that this determination of the HF current flowing *via* the neutral electrode is realized indirectly, namely by a current measuring device at the primary side of the HF circuit or by a current measuring device in the supply line leading to the treatment unit.

It is advantageous here if the memory has a memory discharge control assigned which reduces the integration signal continuously over the whole treatment period.

In accordance with a preferred embodiment, the memory discharge control can reduce the integration signal by the same amount per unit of time, or, preferably, by an amount which is proportional to the integration signal at the beginning of the unit of time.

In accordance with a preferred embodiment, the monitoring circuit can be characterized by a data memory which is assigned to the square-law transfer unit and/or the memory and which stores the amount of the signal corresponding to the square of the HF current and/or the amount of the integration signal during the treatment period in certain intervals.

Further, a comparison unit can be provided which compares the integration signal with a maximum value and which actuates an indication device and/or a switching-off device for the HF current when the maximum value is exceeded.

The following description of a preferred embodiment of the invention serves together with the drawing for a detailed explanation. The drawing diagrammatically shows a monitoring circuit for determining the thermal load on the tissue in a patient in the application area of a neutral electrode.

A high-frequency treatment unit 1 has two connections 2, 3. To the first connection 2, a HF treatment device 5 is switched *via* an anti-faradism capacitor 4, for example a hook electrode. The second connection 3 is connected to a neutral electrode 6 which has a large area and is flatly applied to the body of a patient 7, wherein the electrodes may be known foil-shaped electrodes.

When a patient is treated, the treatment device 5 is advanced with its electrode area towards the tissue of the patient to be treated, so that the patient 7 is switched into the HF circuit. Thereupon, high-frequency current flows from the treatment unit 1 through the treatment device 5, the tissue areas to be treated and other tissue areas of the patient to the neutral electrode 6 back to the treatment unit 1. High current densities are intended to be obtained in the treatment area since the tissue is treated by heat development; contrary thereto, in the area of the neutral electrode 6 in which such heating should be avoided, it is attempted to keep the current density low in that the electrodes are provided with large surfaces.

A measuring device 9 for measuring the effective HF current is switched into the line 8 between neutral electrode 6 and connection 3. It generates an electric signal proportional to the effective current, which is supplied to a square-law transfer unit 11 *via* a line 10. It generates an electric signal corresponding to the square of the effective HF current measured and supplies it to a memory inflow control 13 *via* a line 12. This is controlled by a timer 14 *via* a line 15 and it determines a representative value of the signal supplied by the square-law transfer unit 11 for a certain short period Δt which can *e.g.* be 100 ms.

Since the value of the HF effective current can greatly change during the treatment, it is necessary to determine such a representative value for short time units; this may *e.g.* be done in that integration is performed over all resulting values of the square-law transferred effective HF current in the period Δt, so that the memory inflow control generates a signal which is a measure for the energy which is converted to heat in the period Δt in the area of the neutral electrode.

These individual signals are supplied to an integrating memory 17 *via* a line 16 which integrates these heat amounts converted per time unit Δt over the whole treatment period and thus generates an integration signal which forms a measure of the energy converted to heat by the HF current in the area of the neutral electrode. The integrating memory 17 is connected to a memory discharge control 19 *via* a line 18 which is in turn connected to the timer 14 *via* a line 20. The timer 14 controls the memory discharge control 19 such that it reduces the integration signal of the integrating memory 17 per time unit by a certain amount which can be the same amount for each time unit, however, this amount may also

be proportional to the respective value of the integration signal. This reduction of the integration signal is a measure as to how the heat loss which takes place in the area of the neutral electrode is emitted to the environment, be it by emission, heat dissipation, heat conductance through the body tissue or by convection to the surrounding air.

The integration signal is corrected by the memory discharge control so that it in fact corresponds to the heating behaviour in the area of the neutral electrode 6, so that a low integration signal indicates to a low resulting heating, while a high integration signal indicates to a large resulting heating.

The integration signal generated and, if necessary, corrected by the memory discharge control is supplied to an indication device 22 *via* a line 21 in which the integration signal is compared with a fixed predetermined maximum signal. If the integration signal exceeds this maximum value, the indication device 22 is activated, which then issues warning signals or switches the treatment unit 1 off or reduces the output power therein.

A documentation memory 23 is connected to the output of the memory inflow control 13 and to the integrating memory 17 which stores the signals supplied from the memory inflow control to the integrating memory 17 in accordance with the treatment time and which also stores the respective value of the integration signal generated in the integrating memory 17 during the treatment time. Thus, the whole course of the treatment can be checked in the documentation memory, namely, by the individual energy packets flowing through the neutral electrode per unit of time Δt, on the one hand, and by the overall heating represented by the integration signal, on the other hand. It can thus be checked whether *e.g.* a damage of the tissue in the application area of the neutral electrode 6 was caused by too high a heating or by other effects, such as a pressure necrosis or chemical etching.

The monitoring circuit described can also continue to operate during treatment breaks. In this time, the measured HF current is zero, no signals are supplied to the integrating memory 17 *via* the memory inflow control which could increase the integration signal, however, the integration signal is further reduced *via* the memory discharge control in accordance with the application area of the neutral electrode cooling-down, so that the real conditions in the application area are thereby reproduced. If the treatment is resumed after a longer treatment break, the application area is cooled-down and this is reflected by the fact that the integration signal in the integrating memory 17 has obtained a minimum value which can no more be reduced by the memory discharge control.

Claims

1. A method for monitoring the thermal load on the tissue in a patient in the application area of a neutral electrode of a high-frequency treatment device, **characterized in**
that the HF current flowing through the neutral electrode is measured, a signal corresponding to the square of this current is generated, this signal is fed during the whole treatment duration to an integrator and integrated and the integration signal generated is used as a measure for the thermal load on the tissue.

2. The method according to claim 1, **characterized in that** the HF current flowing through the neutral electrode is determined by a direct current measurement in the line leading from the high-frequency treatment device to the neutral electrode.

3. The method according to claim 1, **characterized in that** the HF current flowing through the neutral electrode is determined indirectly by a current measurement at the primary side in the high-frequency treatment device.

4. The method according to claim 1, **characterized in that** the HF current flowing through the neutral electrode is determined indirectly by a measurement of the supply current flowing to the high-frequency treatment device.

5. The method according to any one of the preceding claims, **characterized in that** the integration signal is continuously reduced over the whole treatment period.

6. The method according to claim 5, **characterized in that** the integration signal is reduced over the whole treatment period by the same amount per unit of time.

7. The method according to claim 5, **characterized in that** the integration signal is reduced over the whole treatment period by an amount per unit of time which is proportional to the integration signal at the beginning of the unit of time.

8. The method according to any one of the preceding claims, **characterized in that** the value of the signal corresponding to the square of the HF current and/or the value of the integration signal during the treatment period is fed to a data memory and stored at certain time intervals.

9. The method according to any one of the preceding claims, **characterized in that** the integration signal is compared with a maximum value, and an indication device and/or a switch-off device for the HF current is actuated when this maximum value is exceeded.

10. Monitoring circuit for monitoring the thermal load on the tissue in a patient in the application area of a neutral electrode of a high-frequency treatment device, **characterized by** a measuring device (9) for determining the HF current flowing through the neutral electrode (6), a square-law transfer unit (11) for generating a signal corresponding to the square of this current, a memory (17) for integrating this signal over the whole treatment period for generating an integration signal as a measure for the thermal load on the tissue.

11. Monitoring circuit according to claim 10, **characterized in that** the measuring device (9) is a current measuring device which is switched into the line (8) between neutral electrode (6) and treatment unit (1).

12. Monitoring circuit according to claim 10, **characterized in that** the measuring device for determining the HF current flowing through the neutral electrode (6) is a direct measuring device which determines the current flowing in the high-frequency treatment unit (1) at the primary side.

13. Monitoring circuit according to claim 10, **characterized in that** the measuring device for determining the HF current flowing through the neutral electrode (6) is formed by an indirect current measuring device which is switched in the current supply line of the high-frequency treatment unit (1).

14. Monitoring circuit according to any one of claims 10 to 13, **characterized in that** a memory discharge control (19) is assigned to the memory (17) which continuously reduces the integration signal over the whole treatment period.

15. Monitoring circuit according to any one of claims 12 to 14, **characterized in that** the memory discharge control (19) reduces the integration signal per unit of time by the same amount.

16. Monitoring circuit according to any one of claims 12 to 14, **characterized in that** the memory discharge control (19) reduces the integration signal per unit of time by an amount which is proportional to the integration signal at the beginning of the unit of time.

17. Monitoring circuit according to any one of claims 12 to 16, **characterized by** a data memory (23) which is assigned to the square-law transfer unit (11) and/or the memory (17) and which stores the amount of the signal corresponding to the square of the HF current and/or the amount of the integration signal during the treatment period in predetermined intervals.

18. Monitoring circuit according to any one of claims 12 to 17, **characterized by** a comparison unit (22) which compares the integration signal with a maximum value and actuates an indication device and/or a switching-off device for the HF current when the maximum value is exceeded.

Translation of the terms used in the drawing

13 - Memory inflow control
17 - Integrator + memory
19 - Memory discharge control
23 - Documentation memory
22 - Indication, warning